

**UNITED STATES DEPARTMENT OF COMMERCE****United States Patent and Trademark Office**

Address: COMMISSIONER OF PATENTS AND TRADEMARKS  
Washington, D.C. 20231

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
-----------------	-------------	----------------------	---------------------

09/372,835 08/12/99 RUSSELL

D 774976.0007-

EXAMINER

MM91/0829

CUMMINGS & LOCKWOOD  
GRANITE SQUARE  
700 STATE STREET  
P.O. BOX 1960  
NEW HAVEN CT 06509-1960

CHURCH, C

ART UNIT

PAPER NUMBER

2882

DATE MAILED:

08/29/01

**Please find below and/or attached an Office communication concerning this application or proceeding.**

**Commissioner of Patents and Trademarks**

## Office Action Summary

Application No.

Applicant(s)

Examiner

Group Art Unit

—The MAILING DATE of this communication appears on the cover sheet beneath the correspondence address—

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, such period shall, by default, expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

### Status

- ☒ Responsive to communication(s) filed on 6/11/01
- ☒ This action is **FINAL**.
- ☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 1 1; 453 O.G. 213.

### Disposition of Claims

- ☒ Claim(s) 20-61 is/are pending in the application.
- Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- ☒ Claim(s) 20-61 is/are rejected.
- ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- ☐ Claim(s) \_\_\_\_\_ are subject to restriction or election requirement.

### Application Papers

- ☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
- ☐ The proposed drawing correction, filed on \_\_\_\_\_ is ☐ approved ☐ disapproved.
- ☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.
- ☐ The specification is objected to by the Examiner.
- ☐ The oath or declaration is objected to by the Examiner.

### Priority under 35 U.S.C. § 119 (a)-(d)

- ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
  - ☐ All ☐ Some\* ☐ None of the CERTIFIED copies of the priority documents have been received.
  - ☐ received in Application No. (Series Code/Serial Number) \_\_\_\_\_
  - ☐ received in this national stage application from the International Bureau (PCT Rule 1 7.2(a)).

\*Certified copies not received: \_\_\_\_\_

### Attachment(s)

- ☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). \_\_\_\_\_
- ☐ Interview Summary, PTO-413
- ☐ Notice of Reference(s) Cited, PTO-892
- ☐ Notice of Informal Patent Application, PTO-152
- ☐ Notice of Draftsperson's Patent Drawing Review, PTO-948
- ☐ Other \_\_\_\_\_

Office Action Summary

Serial No. 372,835  
Art Unit 2882

-2-

Drawings are required.

The following is a quotation of 35 U.S.C. § 103 which forms the basis for all obviousness rejections set forth in this Office action:

A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Subject matter developed by another person, which qualifies as prior art only under subsection (f) or (g) of section 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person.

Claims 20-61 are rejected under 35 U.S.C. § 103 as being unpatentable over Zinreich 5469847. Zinreich teaches a marker system and method comprising radiolucent markers 20 formed from gels comprising barium selected to yield a desired x-ray density under exposure to specified radiation energy so as not to obscure the desired image. See lines 2-5 of column 3 and lines 12-15 of column 6. The per cent attenuation of Zinreich's markers would have been an obvious function of the desired legibility. The Zinreich technique is applicable to any part of a patient's body, and Official notice is taken that the x-ray energy typically employed in medical imaging ranges between 20 and 140 KV. See, for example, *Christensen's Physics Of Diagnostic Radiology*. Lines 12-

Serial No. 372,835  
Art Unit 2882

-3-

15 of column 6 suggest the use of other metals, and aluminum would have been obvious because of its midrange atomic number.

Claims 20-61 are rejected under 35 U.S.C. § 103 as being unpatentable over DeSena (5193106). DeSena teaches a marker system and method comprising adhesive markers 3 bearing patterns formed of barium or aluminum (lines 11-13 of column 3). Lines 62-65 of column 4 suggest that the clarity of the patterns is controlled by their thickness, and It would have been obvious to one of ordinary skill in the art at the time the invention was made to adjust the thickness or % attenuation of the DeSena markers to provide the desired opacity under the specified parameters such as x-ray energy. The DeSena technique is applicable to any part of a patient's body, and Official notice is taken that the x-ray energy typically employed in medical imaging ranges between 20 and 140 KV. See, for example, *Christensen's Physics Of Diagnostic Radiology*.

Applicant's arguments filed June, 2001 have been fully considered but they are not deemed to be persuasive. The declaration by Zielanski asserting commercial success has been considered but is not convincing because applicant was not the first to have invented partially opaque x-ray markers regardless of how successful the commercial product has been.

Applicant misrepresents the Zinreich teaching (page 7 of the amdt) when he proclaims that the Zinreich markers are entirely opaque. Counsel should understand that no material is completely opaque to x rays. Rather its degree of opaqueness or absorption is

Serial No. 372,835  
Art Unit 2882

-4-

a function of its thickness and of the x-ray energy employed. Nowhere does Zinreich proclaim that his markers are completely opaque. Lines 65 of column 3 to 1 of column 4 of the patent does not suggest that the markers are "opaque" as applicant would have one believe. Rather the sentence says

The gel 12 has a mobile phase suitable for MRI imaging by commercial machines and is sufficiently X-Ray opaque for adequate imaging on CT or X-Ray.

"Sufficiently" clearly implies that the markers are only barely visible and certainly are not entirely opaque so as to obliterate the image as applicant construes. Lines 6-12 of column 3 further elucidate

Accordingly it is a principal object of the present invention to provide improved surface markers for use as reference points on diagnostic images and which comprise a gel which is dense to multiple imaging methods such as x-ray, CT, ultrasound, PET, MRI, and others which does not produce undesirable aberrations which obscure portions of the diagnostic images, and which is sealed.

What could be more explicit? ZINREICH'S MARKERS DO NOT OBSCURE THE IMAGE.

Applicant tries to limit the Zinreich markers to CT, but the patent (as in the passage above) clearly specifies x-ray imaging in addition to CT imaging.

Applicant's reading of the DeSena patent are similarly skewed. Lines 62-65 of column 4 of DeSena explain

In the preferred embodiment said aluminum is deposited on to said adhesive tape 1 to a thickness sufficient to highlight an area of interest with clarity.

In other words, the degree of opacity or x-ray absorption is a

Serial No. 372,835  
Art Unit 2882

-5-

function of the thickness of the deposited aluminum, and DeSena instructs that the thickness or blocking power is just enough to make the marker visible in the image. This relationship stems from the principles of physics (Lambert's law states that the amount of x-ray absorption is a function of the density and thickness of the substance that the x rays traverse.), and ignoring them will not render applicant's claims allowable. Nowhere does DeSena suggest that his markers obscure the image as alleged by applicant.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 C.F.R. § 1.136(a).

A SHORTENED STATUTORY PERIOD FOR RESPONSE TO THIS FINAL ACTION IS SET TO EXPIRE THREE MONTHS FROM THE DATE OF THIS ACTION. IN THE EVENT A FIRST RESPONSE IS FILED WITHIN TWO MONTHS OF THE MAILING DATE OF THIS FINAL ACTION AND THE ADVISORY ACTION IS NOT MAILED UNTIL AFTER THE END OF THE THREE-MONTH SHORTENED STATUTORY PERIOD, THEN THE SHORTENED STATUTORY PERIOD WILL EXPIRE ON THE DATE THE ADVISORY ACTION IS MAILED, AND ANY EXTENSION FEE PURSUANT TO 37 C.F.R. § 1.136(a) WILL BE CALCULATED FROM THE MAILING DATE OF THE ADVISORY ACTION. IN NO EVENT WILL THE STATUTORY PERIOD FOR RESPONSE EXPIRE LATER THAN SIX MONTHS FROM THE DATE OF THIS FINAL ACTION.

Any inquiry concerning this communication should be directed to Examiner Church at telephone number (703) 308-4861.

*Craig E Church*

CRAIG E. CHURCH  
Senior Examiner  
ART UNIT 2882